



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

#### **Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence--42 CFR part 8 (OMB No. 0930-0206) and Opioid Treatment Programs (OTPs) - Extension**

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. "Certification" is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form **SMA-162**); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form **SMA-163**); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form **SMA-168**), which may be used

on a voluntary basis by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form **SMA-168** is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: A patient's medical examination when admitted to treatment, a patient's history, a treatment plan, any prenatal support provided the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic attendance, and documentation of physiologic dependence.

The table that follows summarizes the annual reporting burden associated with the regulation, including burden associated with the forms. There are no changes being made to the forms.

Form	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
<b>Estimated Annual Reporting Requirement Burden for Accreditation Bodies</b>					
SMA-163	54	26.055	1,407	0.28	394
<b><u>Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs</u></b>					
SMA-162	651.33	17.976	11,708.91		
SMA-168	1,302.67	17.977	23,418.09		
Subtotal	1954	17.977	35,127	0.08	2902
Total			36,534		3296

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain) . Find this

particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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[FR Doc. 2021-21963 Filed: 10/6/2021 8:45 am; Publication Date: 10/7/2021]